DIAGNOSTIC SERVICES / GENOMICS & HEMATOPATHOLOGY

Change of BCR/ABL p190 Quantitative Molecular Test

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Background

BCR-ABL1 fusion transcript that arises from the minor (p190) breakpoint are predominantly seen in patients with acute lymphoblastic leukemia (ALL); however, the p190 fusion may also be present in a small subset of patients with chronic myeloid leukemia (CML) and even more rarely in acute myeloid leukemia (AML). This quantitative assay is intended for monitoring disease response to therapy and not for diagnostic purpose. Effective November 23, 2020, a more robust method, the QuantideX® qPCR BCR-ABL minor Kit from Asuragen, will be used in place of the former LDT qRT-PCR method. The analytic performance characteristics of the new method have been determined and verified by the Molecular Hematopathology laboratory for clinical use.

Changes in reporting format

- The "Normalized Ratio" will be reported as percentage.
- The linear reportable range of the new assay is from 0.003% to 20%.
- Positive results with the normalized ratio outside of this range will be reported as <0.003% or >20%.

Patient impact

- Sample requirements remain the same.
- A slight shift of normalized ratio (typically within 0.5 log of the ratio) will be expected during the transitional period of method change.
- The new method has a slightly higher sensitivity (normalized ratio of 0.003%) compared to the current one (normalized ratio of 0.04%). Some patients with previously reported negative results may show low positive results using the new assay.

References/Resources:

1. Baccarani M, et al. European LeukemiaNet recommendations for the management of chronic myeloid leukemia: 2013. Blood 2013, 122:872-884.
2. Asuragen QuantideX® qPCR BCR-ABL minor Kit manual

Contact Information:

Dr. Jie Li, Hematopathologist, Diagnostic Services, Shared Health (Ph: 204-787-8692), jli7@sharedhealthmb.ca
Dr. Paul Park, Molecular Pathologist, Diagnostic Services, Shared Health (Ph:204-787-2998), ppark@sharedhealthmb.ca